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510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

OCT 24 2008

Prepared: September 24, 2008

Applicant: Aptis Medical, LLC
3602 Glenview Ave
Glenview, KY 40025
Telephone 502-523-6738
Fax 502-425-7422

Device Name:	Wrist joint ulnar (hemi-wrist) prosthesis
Device Trade Name:	Distal Radio-Ulnar Joint Implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3810
Product Code:	87 KXE
Original Predicate Device:	Distal Radio-Ulnar Joint Implant
Registration Number:	3004521401
Owner Operator Number:	9054354

Device Description:

The ulnar head implant like the predicate device includes various sizes of implants and surgical instruments. The implant allows for replacement of the distal ulnar head.

Indications for Use:

Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
  - Pain and weakness of the wrist joint not improved by non-operative treatment
  - Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
  - Failed ulnar head resection; eg. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

Comparison to the Original Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the same device, the Aptis Medical Distal Radio-Ulnar Joint Implant

Regulatory Class: II
Product Code: 87 KXE

Comparison of original Aptis Medical Distal Radioulnar Joint to the new configuration the additional stem lengths and diameters.

Comparison of current Aptis Medical Distal Radioulnar Joint to the modified device.

Item	*Current Aptis Product*	*Proposed Modifications*
Product Name	Distal Radioulnar Joint Implant	Distal Radioulnar Joint Implant
Use	Single use	Single use
Fixation	stem in intramedulary canal, screw fixation to the distal radius	stem in intramedulary canal, screw fixation to the distal radius
Constraint	Semi constrained	Semi constrained
Material	Co-Cr, UHMWPe, CPTi	Co-Cr, UHMWPe, CPTi
Sizes	2 sizes, 20, 30, body 25 size stems	2 sizes, 20, 30, body 25 size stems
Indications for use	Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:	Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:
	Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:	Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
	Pain and weakness of the wrist joint not improved by non-operative treatment	Pain and weakness of the wrist joint not improved by non-operative treatment
	Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint	Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
	Failed ulnar head resection; eg. Darrach resection	Failed ulnar head resection; eg. Darrach resection
	Primary replacement after fracture of the ulnar head or neck.	Primary replacement after fracture of the ulnar head or neck.
	Revision following failed ulnar head arthroplasty.	Revision following failed ulnar head arthroplasty.

Similarities of the Aptis Medical DRUJ and the slightly modified Aptis Medical DRUJ include;

Both devices are intended for single use only; both devices are intended for surgical implantation longer than 30 days; both devices are placed into the intramedullary canal of the distal ulna; both devices are made of the same industry standard materials. No new materials are introduced in either product; both devices are comparably sized; both devices have the identical indications for use.

Summary:

The device and the predicate device have the same design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aptis Medical, LLC
% Mr. Bryan Babb
3602 Glenview Avenue
Glenview, Kentucky 40025

OCT 2 4 2008

Re: K082839
Trade/Device Name: Distal Radio-Ulnar Joint Implant
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: II
Product Code: KXE
Dated: September 24, 2008
Received: September 26, 2008

Dear Mr. Babb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

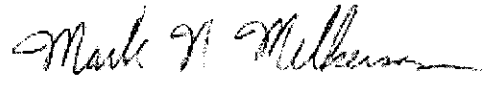
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (If Known): K082839
Device Name: Distal Radio Ulnar Head Implant

Indications for Use:

Aptis Medical Distal Radio Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
  - Pain and weakness of the wrist joint not improved by non-operative treatment
  - Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
  - Failed ulnar head resection; eg. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082839